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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,613	02/29/2000	DEBORAH C. MASH	N08-002	8931

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/486,613	Applicant(s) MASH, DEBORAH C.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a 371 of PCT/US98/18284 which claims priority to provisional application Serial No. 60/057,921.

Election/Restrictions

Applicant's election with traverse of the invention of Group II, Claims 6-9 in Paper No. 7, submitted May 10, 2002 is acknowledged.

The traversal is on the ground(s) that the claimed inventions of Group I and II, claims 1-9, are directed to the same method of alleviating pain in a patient. This is found persuasive as to Groups I-II. Therefore, the Requirement for Restriction is modified as to Groups I and II. Claims 1-9 will be examined on the merits herein.

The requirement between Groups I-II; III and IV is therefore made FINAL.

Claims 10-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. (3,715,361, PTO-1449 submitted May 23, 2000) and GB 841,697 (PTO-1449 submitted May 23, 2000) in view of Bagal et al. (PTO-1449 submitted May 23, 2000) and Hussain (4,464,378, PTO-892) and Applicant's admission regarding the prior art in the specification (see page 1-3).

Epstein et al. discloses that ibogaine and its derivatives are analgesic agents (analgetics), and these agents are therefore useful in treating or alleviating pain. See abstract, col.1 lines 25-38, col.2 lines 1-10 and 33-35 and col.3 lines 1-4.

GB 841,697 discloses that ibogaine is an analgesic agent, and is therefore useful in an analgesic composition for treating or alleviating pain. See abstract, col.1-2, and claims 1-5.

The prior art does not expressly disclose the employment of noribigaine alone or in combination with an opioid antagonist such as naloxone, naltrexone and nalorphine in a method of treating a patient to alleviate pain. The prior art does also not expressly disclose the effective amounts of active agents in the composition herein to be administered.

Bagal et al. discloses that noribigaine is a known active metabolite of ibogaine, and noribigaine enhanced morphine antinociception was more pronounced than with comparable ibogaine treatment. See abstract and page 261 the last paragraph of the right column.

Hussain teaches that opioid antagonists such as naloxone, naltrexone and nalorphine are well known analgesics and therefore useful in a method of treating or

alleviating pain in a patient. See col.1 lines 44 and 56-57, col.3 lines 24-27, and claims 1-2.

Applicant's admission regarding the prior art in the specification (see page 3) teaches that noribigaine is a known metabolite of ibogaine and opioid antagonists such as naloxone, naltrexone and nalorphine are known analgesics and useful in a method of treating or alleviating pain in a patient.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ noribigaine alone or in combination with an opioid antagonist such as naloxone, naltrexone and nalorphine in a method of treating a patient to alleviate pain, and to optimize the effective amounts of active agents in the composition herein to be administered.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ noribigaine alone or in combination with an opioid antagonist such as naloxone, naltrexone and nalorphine in a method of treating a patient to alleviate pain since noribigaine is a known active metabolite of ibogaine. Ibogaine is well known an analgesic agent and is known to be useful in treating or alleviating pain based on the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that noribigaine, a known active metabolite of ibogaine, would have the same therapeutic usefulness being an analgesic agent as ibogaine in the instant method for treating a patient to alleviate pain. Morover, noribigaine is known to possess more effective treatment in the morphine antinociception than ibogaine

according to Bagal et al. Hence, Bagal et al. has also provided the motivation to employ noribigaine in the claimed method.

Further, opioid antagonists such as naloxone, naltrexone and nalorphine are well known to be useful in a method of treating a patient to alleviate pain. Therefore, one of ordinary skill in the art would have reasonably expected that combining noribigaine and an opioid antagonist herein known useful for the same purpose (i.e., treating a patient to alleviate pain) in a composition to be administered would improve the therapeutic effect for alleviating pain. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the effective amounts of noribigaine and an opioid antagonist herein are known in the art. In addition, the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Since all active composition components herein are known to useful to treat a patient to alleviate pain, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. A. Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
July 10, 2002